

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P., and DEY, INC.

Defendants.

C.A. No. 06-113 (JJF)

C.A. No. 06-604 (JJF)

CONSOLIDATED

SEPRACOR INC.,

Plaintiff,

v.

BARR LABORATORIES, INC.,

Defendant.

C.A. No. 07-438 (JJF)

**SEPRACOR'S OPENING BRIEF IN SUPPORT OF ITS  
MOTION TO CONSOLIDATE THE DEY AND BARR CASES**

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February 7, 2008

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### **NATURE AND STAGE OF THE PROCEEDINGS**

Plaintiff Sepracor Inc. (“Sepracor”) filed patent infringement suits under the Hatch-Waxman Act against Dey L.P. and Dey, Inc. (collectively “Dey”), and Barr Laboratories, Inc. (“Barr”), after Dey and Barr filed Abbreviated New Drug Applications (“ANDAs”) with the Food and Drug Administration (“FDA”) seeking approval to market generic versions of Sepracor’s highly successful medication for reversible obstructive airway disease (*e.g.*, asthma), Xopenex® inhalation solution. Dey’s and Barr’s ANDAs contained Paragraph IV certifications alleging that the applicable Sepracor patents were invalid and/or unenforceable.

Pursuant to Federal Rule of Civil Procedure 42(a), Sepracor moves to consolidate for all purposes, including a single bench trial, the three above-captioned Dey and Barr cases pending before this Court that involve the same five patents. This is Sepracor’s opening brief in support of its motion.

### **SUMMARY OF THE ARGUMENT**

The Dey and Barr cases involve the same five patents. The cases have been assigned to the same Judge for disposition. The cases are non-jury cases and therefore will be tried to the Court. Dey and Barr both challenge the validity and enforceability of the five patents. To the extent Dey and Barr raise non-infringement arguments, they are similar and non-specific to the accused products at issue, and involve overlapping claim construction issues.

No trial dates have yet been set. No *Markman* hearings have been held. Although the Dey case is more advanced in discovery, Sepracor is willing to provide Barr access to the discovery that has already occurred in the Dey case (and earlier Breath case) on these same issues. Judicial economy clearly would not be served by having the Court hold two separate trials on the same patents and deciding the same issues twice. Such proceedings would also

increase the burden on the Court and raise the prospect of inconsistent rulings. There is no reason to have separate trials, because the cases have not even been scheduled for pre-trial proceedings and are still early enough in the proceedings to be consolidated.

Assuming the cases will be tried together, which is the most logical and efficient manner to proceed, there is no reason to force separate schedules leading up to the trial. Also, because there is substantial overlap in discovery and claim construction, it makes the most sense to have a single schedule leading to a single trial.

Sepracor has proposed a consolidated schedule, attached at Tab A to this brief, which it submits is a fair and reasonable compromise to finally resolve the litigation relating to the patents in suit in an efficient manner. Because Sepracor is willing in the interest of judicial efficiency to provide Barr with the discovery that has occurred thus far in the Dey case, Barr need only take follow-up or gap-filling discovery. Thus, Barr can catch up to the Dey case without unnecessary burden. For the reasons explained below, Sepracor requests that the Dey and Barr cases be consolidated in accordance with the proposed consolidated schedule attached at Tab A.

### **STATEMENT OF FACTS**

#### **A. The Dey and Barr Cases**

Within 45 days of receiving Paragraph IV notice letters from Dey, Sepracor filed suit against Dey, C.A. Nos. 06-113-JJF and 06-604-JJF (the “Dey cases”), on February 22, 2006 and September 27, 2006 respectively, for infringement of five patents: U.S. Patent Nos. 5,362,755; 5,547,994; 5,760,090; 5,844,002; and 6,083,993. The Dey cases are consolidated under C.A. No. 06-113-JJF. [06-113-JJF, D.I. 77.]

Within 45 days of receiving a Paragraph IV notice letter from Barr, Sepracor filed suit against Barr, C.A. 07-438-JJF (the “Barr case”), on July 12, 2007, for infringement of the same five patents. The Dey and Barr cases are pending before this Court. No *Markman* hearing, final pretrial conference, or trial date has been scheduled for either case.

Sepracor requests that the current schedules in the Dey and Barr cases be amended to a consolidated schedule as reflected in the table below.

Event	Current Dey	Proposed Dates in Barr – No Dates Set by the Court	Sepracor’s Proposed Consolidated Dates
Claim Construction – Initial Briefs	4/10/08	(4/10/08)	04/10/08
Claim Construction – Answering Briefs	5/01/08	(5/01/08)	05/01/08
Close of Fact Discovery	Closed	(9/01/08)	07/01/08
<i>Markman</i> Hearing	Not set	(August 2008)	August 2008
Expert Reports – Initial	Served	(11/12/08)	09/01/08
Expert Reports - Rebuttal	Served	(12/19/08)	10/01/08
Close of Expert Discovery	3/13/08	None proposed	12/15/08
Pretrial Conference	Not set	None proposed	February 2009

**B. Dey and Barr Cannot Obtain FDA Approval of Their ANDAs Until Six-Months After a Launch by a Third-Party, Breath**

As noted above, both the Dey and Barr cases are Hatch-Waxman suits brought under 35 U.S.C. § 271(e)(2). Under the Hatch-Waxman Act, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the first company to file an ANDA with a Paragraph IV certification challenging a patent -- and thus undertaking the risk of litigation -- is given an exclusivity period of 180 days during which period the later-filing generic drug applicants cannot have their ANDAs approved by the FDA. *See* 21 U.S.C. §§ 355(j)(5)(B)(iv) and 355(j)(5)(D).

There is no dispute that neither Dey nor Barr is the first ANDA filer for the generic Xopenex® inhalation solutions at issue.<sup>1</sup> The first ANDA filer is Breath. A suit against Breath is pending in the U.S. District Court for the District of Massachusetts, C.A. No. 06-10043-DPW (the “Breath case”). Therefore, Breath alone is eligible for **180 days** of market semi-exclusivity and that semi-exclusivity precludes Defendants Dey and Barr from marketing their proposed products until some six months *after* Breath has marketed its proposed product. Trial in the Breath case is not scheduled to be concluded until August 1, 2008. Thus, Dey will not be unduly prejudiced if its case is consolidated with the Barr case because Dey cannot obtain FDA approval anyway.

### **ARGUMENT**

#### **A. Consolidation is Authorized by Federal Rule of Civil Procedure 42(a)**

This Court’s authority to consolidate Sepracor’s actions against Dey and Barr for all purposes is well-established:

If actions before the court involve a common question of law or fact, the court may: (1) join for hearing or trial any or all matters at issue in the actions; (2) consolidate the actions; or (3) issue any other orders to avoid unnecessary cost or delay.

Fed. R. Civ. P. 42(a). The Court has broad discretion in matters of consolidation. *See Syngenta Seeds, Inc. v. Monsanto Co.*, No. 04-908-SLR, 2005 U.S. Dist. LEXIS 4651, at \*5 (D. Del. Mar. 24, 2005) (“a district court [has] broad power ... to consolidate causes for trial as may facilitate the administration of justice.”) (*quoting Ellerman Lines, Ltd. v. Atl. & Gulf Stevedores, Inc.*, 339

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<sup>1</sup> There is one small exception not pertinent here. Dey appears to be the first ANDA filer for a generic version of the 1.25 mg/0.5 ml (0.25%) dosage strength of Xopenex® inhalation solution. This does not affect the analysis because Dey cannot obtain approval from the FDA until February 2009 as a result of the 30-month stay of FDA approval caused by the filing of this suit.

F.2d 673, 675 (3d Cir. 1964)). Thus, the district court has ample authority to consolidate proceedings, even over the objections of the parties, to conserve judicial resources and promote efficiency. *Id.*

Courts have routinely consolidated Hatch-Waxman cases against various defendants where, as here, the cases involve the same plaintiffs, same patents, and same branded drug. *See, e.g., Cima Labs, Inc. v. Actavis Group HF*, Nos. 06-1999, 06-1970, 07-893, 2007 U.S. Dist. LEXIS 41516, at \*21-22 (D.N.J. June 7, 2007) (consolidating actions involving the same two patents because “the issues of infringement and validity will likely be similar” and “consolidation will avoid duplication of efforts by the parties”); *Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc.*, Nos. 02-5707, 04-0886, 06-3533-DMC, 2007 U.S. Dist. LEXIS 44996, at \*16-18 (D.N.J. June 20, 2007) (*sua sponte* consolidating actions involving the same plaintiff, same patent, and same branded drug to address the issues “in an efficient fashion”); *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, No. 99-2926, 2001 U.S. Dist. LEXIS 17434, at \*19-\*20 (E.D. Pa. Sep. 28, 2001) (consolidating actions where the issue of patent validity was common to all defendants); *MedPointe Healthcare, Inc. v. Hi-Tech Pharmacal Co.*, No. 03-5550, 2007 U.S. Dist. LEXIS 4652, at \*10-12 (D.N.J. Jan. 22, 2007) (consolidating actions involving different defendants, but the same patent, and same branded drug “because of the similarity in facts, circumstances, and law between the two cases and the potential savings of time and expense to the parties....”).

Consolidating Hatch-Waxman cases results in judicial economy, with little or no prejudice to any party. For example, absent consolidation, the Court would have to preside over separate trials and potentially separate *Markman* proceedings involving identical issues and overlapping proofs and render separate decisions. There is no compelling reason for such

duplication of time and expense on either the Court or the parties. *See Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 06-514-GMS, 2007 U.S. Dist. LEXIS 73198, at \*11 (D. Del. Sept. 30, 2007) (holding “judicial resources likely will be conserved by consolidating these two cases...” involving separate but related patents); *Rohm & Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. 1298, 1310 (D. Del. 1981) (“There is little logic in forcing the Court to educate itself on the intricate factual details and complex legal issues common to both suits on two occasions, in preparation for two separate trials.”).

Indeed, this Court often consolidates cases to avoid duplication of effort. *Syngenta*, 2005 U.S. Dist. LEXIS 4651, at \*10 (consolidating antitrust and patent infringement actions despite “minimal factual and legal overlap” because it would be “more efficient than managing the cases separately.”); *Boehringer Ingelheim Int’l GmbH v. Barr Labs., Inc.*, No. 05-700-JJF (D. Del. Jan. 31, 2006) (order consolidating two Hatch-Waxman cases) (Tab B)); *In re ’318 Patent Infringement Litig.*, No. 05-356-SLR (D. Del. Oct. 20, 2005) (stipulated order consolidating Hatch-Waxman actions) (Tab B); *Waste Distillation Tech., Inc. v. Pan Am. Res., Inc.*, 775 F. Supp. 759, 761 (“Consolidation will encourage orderly pretrial discovery, save witness time and expense, avoid duplicitous filings, and eliminate the risk of inconsistent results between the two proceedings.”)

The reasons for consolidation of the present cases are compelling. As with the numerous consolidated Hatch-Waxman cases cited above, the Dey and Barr cases arise from the filing of ANDAs with paragraph IV certifications concerning proposed generic Xopenex® inhalation solution products. Further, resolution of the Dey and Barr cases requires analysis of the same five patents-in-suit. Both Dey and Barr have alleged similar, if not identical, validity and enforceability defenses. Moreover, Dey and Barr have alleged virtually identical

non-infringement theories relating to the manner in which these types of generic drugs are used (and not anything unique to their respective generic formulations). Consistent with the cases cited above, these substantial factual and legal overlaps are more than sufficient to authorize consolidation under Rule 42(a), which requires only a *single* common issue of law or fact.<sup>2</sup>

Here, consolidation of the Dey and Barr actions for all purposes promotes judicial economy by avoiding “wasteful relitigation” and “duplication of judicial effort.” *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1497 (11th Cir. 1985) (affirming consolidation). For example, if these cases are left on separate tracks, there will be separate trials involving the same five patents, and many of the same fact and expert witnesses. Separate trials would require the same testimony and evidence regarding the patents-in-suit, the same subject matter disclosed in those patents and the same prosecution histories. Given the substantial factual overlap in the Dey and Barr cases, separate schedules would consume far more of this Court’s time and resources than a single consolidated action.

Consolidation also serves the interests of justice because it avoids “inconsistent adjudications of common factual and legal issues.” *Hendrix*, 776 F.2d at 1495 (quoting *Arnold v. Eastern Air Lines, Inc.*, 681 F.2d 186, 193 (4th Cir. 1982)). A consolidated action would avoid any potential for different and possibly inconsistent conclusions regarding discovery matters, claim construction, and ultimately infringement and validity of the five patents-in-suit. It would alleviate any burden on the Court to ensure consistency.

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<sup>2</sup> See, e.g., Wright & Miller, 9A Fed. Prac. & Proc. Civ.2d § 2384 (2007) (consolidation not barred “simply because the plaintiff[ ] may be relying on different legal theories or because there are some questions not common to all the actions; the critical consideration, as in other contexts under the Federal Rules, is whether there is at least one common question”).

Although there is a span of about a year between the consolidated Dey case and the Barr case, courts have ordered consolidation in cases where the litigation is in even more advanced stages, and where the earliest filed case had been pending for more than three years. *Rohm & Haas*, 525 F. Supp. at 1310. The court in *Rohm & Haas* stated that it was “satisfied that any delay occasioned by consolidation is substantially outweighed by the benefits of a single trial.” *Id.*

Further, neither Dey nor Barr will suffer any prejudice from consolidation, particularly because their legal interests are substantively similar. *In re Air Crash Disaster at Florida Everglades On December 29, 1972*, 549 F.2d 1006, 1013 at n.10 (5th Cir. 1977); *Hargett v. Valley Federal Savings Bank*, 60 F.3d 754, 766 (11th Cir. 1995) (upholding consolidation because no prejudice was caused). Dey and Barr both challenge the validity of Sepracor patents-in-suit, and they both seek the ability to produce and market generic versions of Sepracor’s Xopenex® inhalation solution. The questions of law and fact in each determination will be virtually the same, namely the scope of the patents-in-suit and whether defendants’ proposed products infringe these claims. *Magnavox Co. v. APF Electronics, Inc.*, 496 F. Supp. 29, 32 (N.D. Ill. 1980) (“Although defendants contend that each device entails an individual determination of infringement, some of them are similar enough that those questions will be the same.”); *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 834 (Fed. Cir. 1999) (“consolidat[ing] cases arising from the filing of two different ANDA’s with respect to the same patent ... result in judicial and litigant economy.”).

Indeed, consolidation will serve to significantly accelerate the disposition of the Dey and Barr cases compared to their current schedules that provide for them to be tried separately. Moreover, consolidation would not prejudice Dey because, as discussed above, the

Breath ANDA prevents the main product dosage strengths proposed by Dey from being approved anyway. Consolidation would not prejudice Barr because its case is in the early stages. Therefore consolidation will have no real-world impact on Dey's and Barr's marketing of their ANDA products. The balance of little or no prejudice to the Defendants against the substantial lack of efficiency and judicial economy of separate proceedings strongly favors consolidation.

**B. Requested Conditions for Consolidation to Ensure Efficiency**

To ensure that consolidation does not create any unnecessary delay and to create consistency among the parties, this Court should require that Barr take only follow-up or gap-filling discovery. Barr will have access to the relevant fact and expert discovery from the Dey case (and even the relevant discovery from the Breath case), including the document production, pleadings, discovery responses such as interrogatory and request for admission responses, expert reports, and deposition testimony of fact and expert witnesses. Given this and the fact that Barr has not raised any defense that is not already at issue in the Dey and Breath cases, Barr will have virtually all the discovery it needs. However, Sepracor recognizes that Barr should be entitled to any non-duplicative follow-up or gap-filling discovery.

In this connection, Barr's recent motion to the Court for **150** hours of deposition time for fact witnesses, without regard to the deposition testimony that it will receive from the Dey and Breath cases, is an example of why Sepracor's proposed consolidation order will promote efficiency and wasteful relitigation. [07-438-JJF, D.I. 34 at ¶ 5.] In light of all the discovery available to Barr, Sepracor's proposal of 50 hours of deposition is more than adequate and reasonable. In addition, Sepracor proposes that Barr be required to make some showing why it needs to re-depose a witness that has already been deposed in the Dey and Breath cases and to

avoid duplicative questioning at any such deposition. These conditions are fair and will promote prompt and orderly resolution of the Dey and Barr cases.

### **CONCLUSION**

The substantial factual and legal overlap in the actions against Dey and Barr justifies consolidation of these cases for both discovery and trial. Consolidation serves each of the interests underlying Federal Rule of Civil Procedure 42(a) by avoiding the wasteful presentation of the same proofs and witnesses, by conserving the resources of the Court and the parties, and by ensuring a single, consistent view of the facts surrounding issues of infringement and validity of the patents-in-suit. For the foregoing reasons, Sepracor respectfully requests that the Court consolidate the Barr and Dey cases for all purposes.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs Louden*

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February 7, 2008

1487137

**CERTIFICATE OF SERVICE**

I, hereby certify that on February 7, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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**TAB A**

**TAB A**

<b>Event</b>	<b>Consolidated Schedule</b>
Initial Claim Construction Briefs	04/10/08
Answering Claim Construction Briefs	05/01/08
Close of Fact Discovery (Barr case only)	07/01/08
Markman Hearing	August 2008
Initial Expert Reports (Barr case only)	09/01/08
Rebuttal Expert Reports (Barr case only)	10/01/08
Close of Expert Discovery	12/15/08
Final Pretrial Conference	February 2009

**TAB B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FILED  
CLERK U.S. DISTRICT COURT  
DISTRICT OF DELAWARE  
2006 JAN 31 PM 2:37

BOEHRINGER INGELHEIM )  
INTERNATIONAL GMBH and )  
BOEHRINGER INGELHEIM )  
PHARMACEUTICAL, INC., )

Plaintiffs, )

v. )

BARR LABORATORIES, INC., )

Defendant. )

Civil Action No. 05-700-KAJ  
CONSOLIDATED

BOEHRINGER INGELHEIM )  
INTERNATIONAL GMBH and )  
BOEHRINGER INGELHEIM )  
PHARMACEUTICAL, INC., )

Plaintiffs, )

v. )

MYLAN PHARMACEUTICALS INC., )

Defendant. )

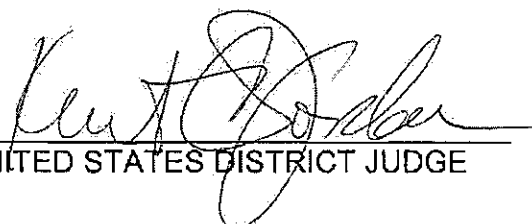
Civil Action No. 05-854-KAJ

**ORDER OF CONSOLIDATION**

At Wilmington this 31<sup>st</sup> day of January, 2006,

IT IS ORDERED that, without prejudice to any parties' right to move for a  
separate trial, C.A. No. 05-700-KAJ and C.A. No. 05-854-KAJ are consolidated.

Hereafter all papers will be filed under C.A. No. 05-700-KAJ.

  
UNITED STATES DISTRICT JUDGE



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )

Plaintiffs, )

v. )

C.A. No. 05-356-KAJ

TEVA PHARMACEUTICALS USA, INC. )  
and TEVA PHARMACEUTICAL )  
INDUSTRIES LTD. )

Defendants. )

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JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )

Plaintiffs, )

v. )

C.A. No. 05-371-KAJ

MYLAN PHARMACEUTICALS INC. )  
and MYLAN LABORATORIES INC., )

Defendants. )

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JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )

Plaintiffs, )

v. )

C.A. No. 05-380-KAJ

DR. REDDY'S LABORATORIES, INC. )  
and DR. REDDY'S LABORATORIES, )  
LTD. )

Defendants. )

JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )

Plaintiffs, )

v. )

C.A. No. 05-381-KAJ

BARR LABORATORIES, INC. )  
and BARR PHARMACEUTICALS, INC. )

Defendants. )

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JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )

Plaintiffs, )

v. )

C.A. No. 05-382-KAJ

PUREPAC PHARMACEUTICAL CO. )  
and ALPHARMA, INC. )

Defendants. )

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JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )

Plaintiffs, )

v. )

C.A. No. 05-420-KAJ

ALPHAPHARM PTY., LTD. )

Defendant. )

JANSSEN PHARMACEUTICA N.V.,	)	
JANSSEN, L.P., and	)	
SYNAPTECH, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. 05-451-KAJ
	)	
PAR PHARMACEUTICAL, INC. and	)	
PAR PHARMACEUTICALS	)	
COMPANIES, INC.,	)	
	)	
Defendants.	)	

**STIPULATED CONSOLIDATION ORDER**

Consistent with the discussion during the October 12, 2005 Rule 16 scheduling conference in the captioned cases (collectively, the "Actions"), all seven of which involve common questions of law and fact within the meaning of Fed. R. Civ. P. 42(a),

IT IS HEREBY STIPULATED AND AGREED, subject to the approval and order of the Court, as follows:

1. The Actions are consolidated for all pretrial purposes and trial.
2. All discovery conducted to date in any of the individual seven captioned cases shall be treated as having been conducted in this consolidated litigation.
3. Papers submitted in this consolidated litigation shall be filed and docketed solely in C.A. No. 05-356-KAJ.
4. All filings in this consolidated litigation shall bear the following consolidated caption:

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	
	)	C.A. No. 05-356-KAJ
	)	(consolidated)

ASHBY & GEDDES

*/s/ Steven J. Balick*

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SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_ 2005.

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United States District Judge